



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,007	01/18/2006	Anne-Marie Pinel	34930158PUS1	7203
2292 7590 05/02/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER AUDET, MAURY A				
ART UNIT		PAPER NUMBER		
1654				
NOTIFICATION DATE		DELIVERY MODE		
05/02/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

### Office Action Summary

**Application No.**

10/565,007

**Applicant(s)**

PINEL ET AL.

**Examiner**

MAURY AUDET

**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-17, 19, 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-17, 19, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

As noted previously, the present application has been transferred from former Examiner Young to the present Examiner.

Applicant's amendment, affidavit (as to 112 1<sup>st</sup> scope) and response of 12/19/08 are acknowledged.

### ***Election/Restrictions***

As noted previously, Applicant's election with traverse of Group II, claims 12-14, 16, and 17, in the reply filed on 3/26/07 is acknowledged. The traversal is on the ground(s) that the prior art cited no longer teaches the invention, at least part, based on the amended claims. This Examiner agrees based on the negative limitation provided ("not coupled with zinc"), and the traversal is thus deemed moot (although the original restriction groups are maintained for the reasons of record). This Examiner is willing to rejoin claims 15 and 19 as well.

The requirement is still deemed proper and is therefore made FINAL. Claims 12-17, 19, and new claim 23 are pending and examined on the merits.

### ***Claim Rejections - 35 USC § 112 1<sup>st</sup> Written Description***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 12-17, 19, and 23 and new claim 24 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

Art Unit: 1654

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is maintained for the reasons of record. Applicant's response has been fully considered but are not found persuasive. Namely, Applicant argues that since "most" amino acids can exist as two distinct optical isomers called D and L, as noted in references such as Wikipedia's article on "Isomerism", that one of skill in the art could immediately envisage "which" enantiomers or diastereomers Applicant was in "possession" of at the time of the invention. This is not found persuasive for the reasons of record. As there are a number amino acids in said peptides of the invention, it is not clear which will or are meant to isomerize, and what the ultimate structure of said enantiomers or diastereomers Applicant actually had "possession" of at the time of the invention.

The rejection is repeated below for continuity of record:

This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

*Vas-Cath Inc. V. Mahurka*, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

The claimed invention is drawn to the use of a peptide conjugate formula of core tripeptide Gly-His-Lys (and specifically SEQ ID NOS: 5-14) for the treatment of alopecia and

hair loss, including any form of enantiomers, diastereoisomers, mixtures thereof, including racemix mixtures of said peptide conjugate.

One of skill in the art would not recognize from the disclosure that the Applicant was in possession of the claimed genus of any form of enantiomers, diastereoisomers, mixtures thereof, including racemix mixtures of said peptide conjugate. The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed” (see *Vas-Cath* at page 1116). Namely, although the specification describes peptide conjugates containing the tripeptide Gly-His-Lys, no enantiomers, diastereoisomers, mixtures thereof, including racemix mixtures were found to be described.

Thus, neither the claims nor the specification adequately describe the claimed genus of any enantiomers, diastereoisomers, mixtures thereof, including racemix mixtures, comprising the tripeptide conjugate comprising Gly-His-Lys. With the substantial variability among the broad genus, contemplating any such variants of the above peptide conjugates, it is not recognizable what the structure of these variants would be? One of skill in the art would not recognize from the disclosure that the Applicant was in possession of the genus, namely any form of enantiomers, diastereoisomers, mixtures thereof, including racemix mixtures of said peptide conjugate comprising the tripeptide conjugate comprising Gly-His-Lys.

#### ***Claim Rejections - 35 USC § 112 2nd***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained based on amendment.

Claim 12 is still rejected, as “X represents” recites “a bond” twice and is duplicative.

### ***Claim Observation***

In claim 12, it is suggested that Applicant consider opening with the term “A” in line 1 and remove the second recitation of “of” for clarity.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th, 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).  
MA, 4/20/2007

/Cecilia Tsang/  
Supervisory Patent Examiner, Art Unit 1654